

### REMARKS

The invention generally relates to a bone replacement mixture, in particular, calcium phosphate compounds which are capable of being chemically compatible with bone and hard tissue material *in vivo* mixed with at least first and second macropore forming materials which increase the flexural strength of the mixture *in vivo* by at least 50% and which, in due course, dissolve. The rate of dissolution of the macropore forming materials may be the same or may vary. However, the dissolution rate is dependent upon the choice and combination of macropore forming materials so that the dissolution rate *in vivo* is at least about a week.

The invention enables bone replacement therapy wherein the bone material is subject to significant stresses. Heretofore, such bone replacement therapy has not been practicable. By providing the mixture of a bone replacement compound in combination with macropore forming materials selected to increase the strength of the mixture and which over time will dissolve, one enables the body to adopt the replacement materials *in vivo* in circumstances where the bone replacement requires significant structural integrity.

Independent claim 1, as amended, thus includes certain limitations which are not taught in the prior art. For example, the mixture requires the use of macropore forming materials which have certain characteristics *in vivo*. The characteristics include dissolution and, perhaps most importantly, increasing the flexural strength of the mixture by at least 50%. Thus claim 1 has been amended to incorporate the limitation of the *in vivo* mixture of materials, as discussed above, and the strength characteristic.

In contrast, the prior art merely discloses a method of making a macropore ceramic by mixing polyethylene and ammonia carbonate. The material is then heated and the pore forming

agents are burned out at a high temperature. The pore forming agents are, of course, burned out prior to implant *in vivo*. Hence, the pore forming agents do not increase the implant strength and are not useful *in vivo*. By contrast, the agents of the presently claimed invention substantially increase the implant strength and do so *in vivo*.

The prior art pore forming agents cannot therefore be tailored to provide a dissolution rate *in vivo* to match a bone healing rate, again *in vivo*. In the present invention, the macropore forming materials are retained in the bone replacement mixture during the period of time when the material is within the body and provide the additional strength necessary to make the implant effective in high stress environments, particularly at the beginning of the implant therapy. Note that various forms of the macropore forming materials and various dissolution rates are taught to enable customized control of the *in vivo* bone replacement therapy.

Again, this advance is clearly distinct from the prior art. For example, the Real reference teaches that the bone cement strength decreases as a result of the combination taught therein. The German reference to Biovision teaches that the mixture is sintered prior to implant. Obviously, this would not work *in vivo*.

For the foregoing reasons, it is believed that the claims in their amended condition are allowable. Reconsideration and passage to allowance is earnestly solicited.

With respect to the undated references in the Information Disclosure Statement, Applicant, on information and belief advises their publication prior to the filing date of the present application. Applicant requests their consideration by the Examiner.

Respectfully submitted,

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